



NUCLEAR ENERGY INSTITUTE

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July 19, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Reference: Request for Comments on Advance Notice of Proposed
Rulemaking, 21 CFR Part 179 [Docket No. 98N-1038]
Irradiation in the Production, Processing, and Handling of Food.
(64 FR 7834, February 17, 1999)

Dear Sir:

The Nuclear Energy Institute¹ (NEI) appreciates the opportunity to comment on the Food and Drug Administration's (FDA) advance notice of proposed rulemaking for labeling requirements for foods treated with ionizing radiation. We fully support the use of ionizing radiation in the production, processing and handling of food. NEI agrees with the American Medical Association and the U.S. Public Health Service on this application of nuclear energy. Food irradiation makes food safer, keeps it fresh longer, and teamed with proper handling and cooking, makes for a healthier population.

NEI supports the continued use of the current wording of the radiation disclosure statement. In lieu of a specified date for the labeling requirement to expire, we recommend the FDA reconsider the labeling requirement in five years. After five years of use the FDA will have more information on consumers' experience with irradiated food.

¹ The Nuclear Energy Institute is the organization responsible for establishing unified nuclear industry policy on matters affecting the nuclear energy industry. NEI's purpose is to foster and encourage the continued safe utilization and development of nuclear energy to meet the nation's energy, environmental and economic goals. NEI represents over 250 companies and organizations worldwide, including electric utilities that own and operate nuclear power plants, nuclear plant equipment suppliers, engineering/construction firms, nuclear fuel cycle companies, and others in the nuclear energy industry.

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NEI also supports the use of the international radura symbol in conjunction with the disclosure statement. However, use of the symbol should be optional and it should not be relied upon as the sole identification. The radiation disclosure statement should be as prominently displayed as the declaration of ingredients, but not more so. It should be limited to packages whose major ingredient/content was treated with radiation. As you are aware, most spices are treated with irradiation. If the labeling requirement was extended to include any irradiated ingredients, most processed and packaged foods containing any form of seasoning, would require the labeling. This would be an over extension of the application.

NEI also suggests the FDA recognize and proactively address the skepticism shown by the American public to new products or processes. In the case of irradiation the public is more skeptical than normal. Therefore, we suggest that the FDA and related branches of government be proactive and allocate funds to educate the public on the benefits of food irradiation so they will not be misled by the labeling requirements.

Responses to the questions posed in the Federal Register notice are presented below:

(1) Does the current radiation disclosure statement convey meaningful information to consumers in a truthful and nonmisleading manner?

The current radiation disclosure statement conveys the information the consumer needs in order to make an informed decision on purchasing the product.

(2) How do consumers perceive the current radiation disclosure statement - as informational, as a warning, or as something else?

The disclosure statement is perceived differently by different types of consumers. The informed consumer who understands the benefits of radiation sees the statement as positive information. They use this information to select an irradiated product over one that has not been irradiated. The consumer who has concerns about the risks of radiation sees the statement as positive information so they can select another product that has not been irradiated.

(3) Does the wording of the current radiation disclosure statement cause "inappropriate anxiety" among consumers? What are examples of "inappropriate anxiety"?

NEI does not believe the current radiation disclosure statement causes “*inappropriate anxiety*” among typical consumers. However, there is a small percentage of consumers who have anxiety with the use of radiation or some other treatments used for food safety. A consumer having an abnormal fear of radiation in general, will also have inappropriate anxiety with the use of radiation. No matter how the radiation disclosure statement is presented to these consumers they would react the same. It isn’t the statement as much as the other fears and concerns that are prompted by the statement.

(4) What specific alternate wording for a radiation disclosure statement would convey meaningful information to consumers, in a truthful and nonmisleading manner, and in a more accurate or less threatening way than the current wording?

The limited research conducted for NEI did not identify any alternate terms, wording, or phases that were more effective than the current radiation disclosure statement.

(5) Would consumers be misled by the absence of a radiation disclosure statement in the labeling of irradiated foods? Are consumers misled by the presence of such a statement?

Since irradiated food is new to the market, the consumer has the right to know and select it over food that has not been irradiated. Without the statement the consumer may be misled into believing food has undergone radiation when it has not. The consumer would not be misled by the presence of the statement.

(6) With respect to foods containing irradiated ingredients, are consumers misled by the absence of a radiation disclosure statement? Would consumers be misled by the presence of such a statement?

Consumers are not misled by the absence of the radiation disclosure statement. As discussed above, most spices have been irradiated. If the radiation statement was used, based on these ingredients, most processed foods would require the statement. It is not reasonable to go to this degree. However, if the major ingredient/component of the processed food was irradiated it would be reasonable to include the radiation disclosure statement on the package label.

(7) What is the level of direct consumer experience with irradiated foods that are labeled as such?

The consumer has had little experience with irradiated foods in the United States. In demonstration programs that have been carried out in various parts of the country consumer acceptance has been acceptable to high. However, it has required a significant education and advertising program to achieve this.

(8) What is the effect of the current required labeling on the use of irradiation? Does the current required labeling discourage the use of irradiation?

Due to the limited use of irradiation there does not exist a good measure of the effect of the current labeling requirements. The labeling requirement does discourage food processors from using irradiation. They are not confident the public would accept irradiated food. Due to the highly competitive market and the use of brand names, companies feel the downside risk of the public not accepting the irradiated products and the slightly higher cost of production are not outweighed by the longer shelf lives and improved food safety.

(9) What do consumers understand to be the effect of irradiation on food? For example, what do consumers understand about the effect of irradiation on the number of harmful microorganisms in or on food?

The informed consumer understands the benefits of food irradiation. They know that irradiation eliminates a large number of the harmful microorganisms, but not all of them. They also understand that even with irradiation proper food handling and preparation is necessary to prevent spoilage of food.

(10) Do consumers readily recognize the radura logo?

Since the radura logo has had limited usage in the United States most consumers would not recognize it.

(11) Do consumers understand the logo to mean that a food has been irradiated?

Due to the limited exposure the consumer would not understand the significance of the radura logo. After a few years of wide spread usage in the United States the consumer would readily recognize and understand it.

(12) Do consumers perceive the radura logo as informational, as a warning, or as something else?

The informed consumer sees it as informational. The uninformed consumer sees it as a pretty package decoration.

(13) Should any requirement for a radiation disclosure statement expire at a specified date in the future?

Due to the limited experience with irradiated food in the U.S. it is premature to anticipate expiration requirements for radiation disclosure statements. NEI recommends that the FDA reevaluate the radiation disclosure statement requirements on some established frequency, such as every five years, instead of specifying an expiration date at this time.

(14) If so, on what criteria should expiration be based?

Expiration should be based on the common usage of irradiation in the food processing industry. When the consumer routinely expects that the food has been irradiated, it would be appropriate to discontinue the labeling requirements.

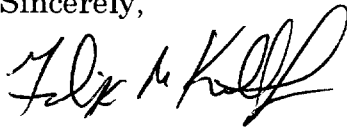
(15) If the expiration of labeling requirements for irradiated foods is to be based on consumer familiarity with the radura logo and understanding of its meaning, what evidence of familiarity and understanding would be sufficient to allow these requirements to expire?

NEI does not believe the radura logo can be used as a substitute for the radiation disclosure statement. The radura logo can be used to help identify irradiated food for the informed consumer, but it should not be relied upon for the sole identification while the radiation disclosure statement requirement remains. If food irradiation becomes the norm, and the radiation disclosure statement requirement is removed, the food producer should not be prohibited from using the radura logo for irradiated food identification.

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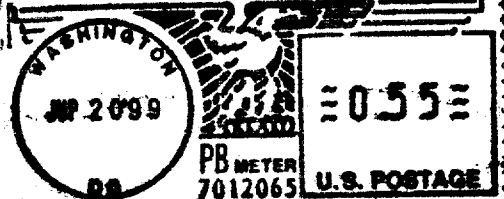
In conclusion, NEI supports the use of the radiation disclosure statement. We believe, with usage, the consumer will seek irradiated food over non-irradiated food. To insure the consumer has the necessary information to make educated decisions on selection of irradiated vs. non-irradiated food, the package must carry the label. If you have any questions concerning the answers to the questions or any of the information we provided, please contact me.

Sincerely,

A handwritten signature in black ink, appearing to read "Felix M. Killar, Jr.", written in a cursive style.

Felix M. Killar, Jr.

c: Committee on Radionuclides and Radiopharmaceuticals



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